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TITLE: "Develop a Prototype Personal Health Record Application (PHR-A) that Captures Information About Daily Living Important for Diabetes and Provides Decision Support with Actionable Advice for Diabetes Self Care".


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**14. ABSTRACT**

The overarching vision of this project is to help people with diabetes better manage their condition by providing them with a tool that will make self-management less confusing, less stressful, and less constrained. This is a two-phase project. In phase 1, we designed an Internet-based and mobile application (software) to assist with the following domains pertinent to diabetes self-management: 1) nutrition/diet (healthy eating) 2) physical activity (being active); 3) blood glucose (self-monitoring); 4) medications (tracking and adherence only); 5) outlook and beliefs; and 6) reducing risks through recommended medical visits, lab testing. Although not a primary focus, the application also addresses weight management and loss. The application is called Tracking My Diabetes (TMD). Using information that TMD receives on these self-management domains (from the user's own monitoring/journaling devices that store data in Microsoft HealthVault and/or from the user's manual data entry directly into TMD), TMD analyzes, interprets, provides feedback, and makes recommendations bolstered by educational content on diabetes self-management. All of the feedback and recommendations are focused on lifestyle. Some feedback provides information on the relationships among the various self-care domains. In phase 2, the project is conducting a brief pilot study of the clinical efficacy of the PHR-A in people with diabetes. The main outcome is glycemic control.

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## INTRODUCTION

Despite the well-documented benefits of glycemic control[1,2] and a secular trend to overall improvement in people with diabetes,[3] glycemic control is still sub-optimal in many patients. According to the National Health and Nutrition Examination Survey, 43.2% of people with diabetes had A1c levels greater than or equal to the generally recommended target of 7.0%.[3] Achieving target glycemic control typically requires a multi-factorial approach, with considerable commitment from the person with diabetes to examine and correctly interpret random blood glucose readings, take medications as prescribed, follow a balanced, whole foods-based diet and engage in regular physical activity. For a variety of reasons, many people with diabetes do not or cannot adhere to these requirements;[4-8] failure to do so may be due to inadequate education about the purpose and outcomes of such behaviors and the absence of support and/or reminders.

Thus, the overall objective of this project is to develop (phase 1) and test (phase 2) a new tool for diabetes self-management that provides education, reminders, and support. The new tool is an internet-based and mobile application (software), now called Tracking My Diabetes (TMD). Our central hypothesis is that an application (such as TMD) that coordinates the major components of diabetes self-management, is mobile, provides decision support with actionable options, and is based on user input, will enhance diabetes self-care, improve glycemic control, and lower psychological distress related to diabetes. During development (phase 1), we created the functional requirements, rules and algorithms for TMD, and then coded these rules and algorithms to create a functioning, Internet-based tool. The study (phase 2) is a test of the TMD's clinical efficacy when used for 3 months by a cohort of people with diabetes.

## BODY

### *TASK 1. Draft functional requirements -- COMPLETE*

This is the first task that the project completed, and is foundational for the rest of the work. **THIS INFORMATION HAS BEEN REPORTED PREVIOUSLY, BUT WE INCLUDE IT HERE FOR CONTINUITY OF DOCUMENTATION.**

To complete this task, the project identified, discrete, user-friendly 'modules' that address the main components of diabetes care. The modules, borrowed from the American Association of Diabetes Educators are:

- Healthy Eating
- Being Active
- Outlook
- Medications
- Monitoring (weight and blood glucose)
- Reducing Risks

Although not a separate module per se, the application also includes weekly diabetes tips (or twice weekly, depending on user preference) that cover the above areas (the user chooses the areas). We have drafted tips pertaining to the above areas.

Furthermore, the 'Reducing Risks' module is not stand-alone; rather it is incorporated into the user's Home Page and addresses issues such as lab results and appointment reminders.

We submitted the Functional Requirement Document (Task 1) to Stacey Zimmerman. The following is excerpted from the Functional Requirement Document submitted. ***We are including this information here because the contract transitioned from the TRUE Research Foundation to the Geneva Foundation, resulting in a new contract number, and we are not sure if all artifacts of the project were transferred with it. Note, the second task describes changes to the requirements that came out of our process for obtaining feedback.***

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**START OF EXCERPT FROM FUNCTIONAL REQUIREMENTS DOCUMENT**

### A. Operating Environment

The PHR-A is a web-based application that consists of:
- Two user interfaces
  - o An HTML and JavaScript browser-based front end designed for the desktop
  - o An HTML and JavaScript browser-based front end designed for mobile Smartphones
- A Java-based framework utilizing Apache Struts on the server
- Relational database to handle data storage requirements

### B. PHR-A Technical Requirements Summary

**Technical Architecture / Deployment Module**
The PHR-A must be designed to be deployed as one universally-available application.
Specific technical architecture guidelines can be found in the PHR-A Technical Architecture Document.

**User Prerequisites**
While intended to support the person with diabetes, the PHR-A will be publicly-available to anyone interested in using it. No formal training is required. However, some baseline familiarity with internet technologies will be necessary to interact with the various application modules.

Use of the desktop browser Version requires only basic internet connectivity and a reasonably modern computer.

Use of the mobile Version requires a device with both internet connectivity and an internet browser.

Some components of the PHR-A utilize data from third-party Personal Health Record (PHR) data repositories, such as Microsoft HealthVault. In order to take advantage of those components users will be required to both create their personal account and facilitate the transfer of their personal health record information.

## Hardware Requirements

The PHR-A has the following hardware requirements:

| System | Type | Requirements |
|---|---|---|
| BEA Weblogic | Application Server | • Server class machine with Windows 2003/8 Server |
| | Communications | • TCP/IP |
| Oracle 10g | Database Server | • Server class machine with Windows 2003/8 Server |
| | Communications | • JDBC |
| PHR-A Client | Desktop Client | • Desktop class machine with Windows XP SP2 or newer |
| | Mobile Client | • Smartphone with connectivity to the Internet |
| | Communication | • TCP/IP<br>• HTTP 1.1<br>• HTTPS 1.1 |

## Software Requirements

The PHR-A has the following software requirements:

| System | Requirements |
|---|---|
| Application Server | • BEA Weblogic Express 9.2 or higher<br>• Java v5Apache Struts v2<br>• Hibernate v2<br>• C3PO<br>• SQL*Net client / JDBC |
| Database Server | • Oracle 10.0.2 |
| Desktop Client | • Internet Explorer v6/5 or<br>• Firefox v3.5 or<br>• Safari 4 |
| Mobile Client | • Javascript/EMCAScript enabled Mobile Browser |

## Technology Requirements

The recommended technologies are as follows:

| Technology | Use | Requirements |
|---|---|---|
| Java | Application | Provides the backend application software to drive the PHR-A |

| BEA Web Logic | Application Hosting | Application server, which hosts the Java application |
|---|---|---|
| Oracle 10 | Data Storage | Robust data storage for PHR-A data |
| HTML/JavaScript | Client-browser presentation | Markup language used to display information in a web browser and interact with the user |

## Development Environment

### Software

| Tool | Purpose |
|---|---|
| Eclipse | Java development environment |
| ERWin | Data Modeling |
| Oracle 10g | Database |
| Apache Tomcat v5.5 or higher | Application Server |
| Java Virtual Machine v5 | Java runtime environment |

## Desktop User Interface Guidelines

The following user interface guidelines should be used in implementing the desktop Version of the PHR-A.

1. Desktop page size will be optimized for a resolution of *1024 x 768 pixels*. The application will be usable at lower resolutions, but may require horizontal and vertical scrolling.
2. The application will be targeted for multi-browser support.
3. Each page of the application will contain a page title.
4. The desktop client will display the username of the user who is logged in, a link to logout, and a link to access the user's personal settings.
5. For all date fields the following behaviors will be implemented:
    a. A Calendar should be enabled for all date fields that are not likely to have dates older than 5 years entered to allow the user to graphically select the date.
    b. If the user enters only a 4 digit year the date will default to "01/01" of the entered year.
    c. If the user presses the "t" key on the keyboard in the date field the current date will display.
6. The user will be able to sort the contents of a panel within the desktop client by clicking on the column header within the Panel.
    a. The first click on a column header will sort the data in ascending order.
    b. The second click on the same column header will sort the data in descending order.
    c. Subsequent clicks on the same column header will alternate the sort order between ascending and descending.
7. Data entry pages will exhibit the following interface behaviors:
    a. Required fields are designated by using a red "*" to the left of the field label. Additionally a "* = Required Field" text will display on the page.
    b. A message prompt will display if the user is editing or adding data and navigates away from the page. The prompt will display a message that the data were not saved and the user can cancel the navigation or proceed without saving.

c. Users of the desktop client will be able to navigate through the fields via the TAB key on the keyboard.  Default tab movement will be from starting at the top and moving left to right then top to bottom.  Within the sections where the tabbing is different than the default a special requirement/consideration will state this fact.

8. The application will provide context sensitive tool tips (mouseover messages) as much as possible to aid the use and navigation of the user.

## Mobile Client User Interface Guidelines

The following user interface guidelines should be used in implementing the mobile Version of the PHR-A.

1. Mobile page size will be optimized for a resolution of 480x854 *pixels*. The application will be usable at lower resolutions, but may require horizontal and vertical scrolling.

2. The application will be targeted for multi-browser support.

3. Each page of the application will contain a page title.

## Development Best Practices

To the extent feasible, the PHR-A will follow both the mobile website and mobile application best practices published by W3C. The current Versions of these practices may be accessed with the following URLs:

1) http://www.w3.org/TR/mobile-bp/
2) http://www.w3.org/TR/mwabp/

## Special Testing Tools/Constraints

The mobile Version of the PHR-A requires a Smartphone. Smartphone technologies evolve very rapidly and vary widely between both manufactures and network carriers. The PHR-A will be designed to work on the widest range of devices possible; however it will not be possible to fully test every device on every network. Initial development testing will utilize the desktop computer based phone / mobile browser emulators typically made available to application developers by the device manufactures. Additional information on emulators and a best practices testing approach may be found at http://mobiforge.com/testing/story/a-guide-mobile-emulators.

After initial emulator based testing is complete, the software will be formally tested using the default web browser applications on the following popular Smartphones:

- Apple iPhone (AT&T 3G network/Apple OS)

- Blackberry Storm2 (Verizon 3G network/Blackberry OS)

- Motorola Droid (Verizon 3G network/Google OS)

- Samsung Omnia (Verizon 3G network/Windows OS)

## C. System Functional Requirements

### General

The PHR-A will consist of three modalities for viewing content and using the application functionality. These are the PHR-A website, iGoogle, and a mobile Smartphone. The PHR-A website will be viewable in a Smartphone browser, but will not be optimized for the screen size and resolution, only specific content will be optimized. Certain functions may be limited to specific modalities and this will be noted in each section's requirements.

### PHR-A Website

The PHR-A website is the user's introduction to the PHR-A and will serve as a general marketing and informational website. It will allow the user to create an account and access the system functionality. Certain functionality will only be available within the PHR-A website.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|--------|------------------|-------------|----------|-----------|
| PHRA_Website1 | General Application and Module Information | The system shall present a publically-available website which describes the PHR-A; provides detailed information on the function and use of each module; provides links for adding selected modules to the users portal framework | 1.0 | 1.0 |
| PHRA_Website2 | Account Management | The system shall allow users to sign up for PHR-A services; manage their account and configure their personal preferences | 1.0 | 1.0 |
| PHRA_Website3 | Account Setup | The system shall present users with an initial setup process | 1.0 | 1.0 |
| PHRA_Website4 | Module Usage | The PHR-A modules must be usable within the website itself and not require the use of iGoogle or mobile phone to view and use | 1.0 | 1.0 |

### iGoogle

Individual modules can be used within iGoogle as gadgets.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|--------|------------------|-------------|----------|-----------|
| iGoogle_1 | iGoogle Framework | The iGoogle framework must be available to all users and manages the user's ability to view, execute, add, drop and arrange PHR-A modules as desired | 1.0 | 1.0 |
| iGoogle_2 | Module Usage | The PHR-A module must be usable within the iGoogle framework | 1.0 | 1.0 |

### Mobile Smartphone

Individual modules can be viewed on a Smartphone browser.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|--------|------------------|-------------|----------|-----------|

| Smartphone_1 | Module Usage | The PHR-A modules must be usable on a mobile Smartphone browser | 1.0 | 1.0 |
|---|---|---|---|---|

## PHR-A Website Requirements

### Create Account

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| CreateAccount_1 | Account Creation | They system must allow the user to create an account | 1.0 | 1.0 |
| CreateAccount_2 | Account Confirmation | The system must send a confirmation email to the user before the account becomes active | 1.0 | 1.0 |

### Login/Logout

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| Login_1 | Login to PHR-A | The system must allow users with current security rights to successfully access the PHR-A content | 1.0 | 1.0 |
| Login_2 | Logout of PHR-A | The system must allow users to successfully logout of the PHR-A | 1.0 | 1.0 |
| Login_3 | Timeout of PHR-A | The system must automatically logout the user after a system configurable time period has expired | 1.0 | 1.0 |

### Password Management

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| PasswordMngmt_1 | Password Reminder | The system must be capable of sending a new temporary password reminder to the user upon request by the user after correctly responding to a series of challenge questions | 1.0 | 1.0 |
| PasswordMngmt_2 | Password Change | The system must allow the user to change their password | 1.0 | 1.0 |
| PasswordMngmt_3 | Challenge Phrase | The system must allow the user to change the challenge phrase and answers | 1.0 | 1.0 |
| PasswordMngmt_4 | Temporary Password | The system shall require the user to immediately change a temporary password after successfully logging | 1.0 | 1.0 |

### Initial Setup

Upon initial creation the user will be guided through an initial setup process by which they can set application preferences and learn about the PHR-A.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|

| REQ ID | | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| InitialSetup_1 | Initial setup | They system must guide the user through an initial account setup | 1.0 | 1.0 |

## Account Personalization

The user will be able to update their account information.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| AccountPersonalization_1 | Account Update | The system must allow the user to update their account information. | 1.0 | 1.0 |

## Microsoft HealthVault Account Setup

Use of Microsoft HealthVault is not required, but the PHR-A can synchronize with Microsoft HealthVault.
To do so, the user must give the PHR-A explicit permission

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| HealthVault_1 | HealthVault Initialization | The PHR-A must have the ability to synchronize the user's account with their Microsoft HealthVault account according to Microsoft's published guidelines | 1.0 | 1.0 |

### D. General Module Requirements

Modules represent individual functional areas within the application. The following requirements pertain to each individual module.

## Module Presentation

Modules can be presented in a number of different modalities.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| ModuleOverview_1 | Website Presentation | Modules must be presentable within the PHR-A website | 1.0 | 1.0 |
| ModuleOverview_2 | iGoogle Gadget Presentation | Modules must be presentable within iGoogle as a Gadget | 1.0 | 1.0 |
| ModuleOverview_1 | Mobile Presentation | Modules must be presentable within the browser on a Smartphone | 1.0 | 1.0 |

## Secure Login/Logout

The following requirements address entering and exiting secured PHR-A modules.  Not all modules will have a security requirement but login may still be required for accurate system usage monitoring.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|

| Login_1 | Login to PHR-A | The system must allow users with current security rights to successfully access the PHR-content | 1.0 | 1.0 |
|---------|----------------|------------------------------------------------------------------------------------------------|-----|-----|
| Login_2 | Reset User Password | The system must allow users to reset their password after attempting to access the PHR-A with an expired password. | 1.0 | 1.0 |
| Login_3 | Logout of PHR-A | The system must allow users to successfully logout of the PHR-A | 1.0 | 1.0 |
| Login_4 | Forgot User Password | The system must allow users to request a new password if the password was forgotten.  The system should provide a new temporary password via email | 1.0 | 1.0 |
| Login_5 | Password Expiration | The user's password should expire after a system configurable time frame | 1.0 | 1.0 |

## Password

Password requirements will follow DoD standard password requirements.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|--------|------------------|-------------|----------|-----------|
| Password_1 | Length | The system must require a password be at least 10 characters | 1.0 | 1.0 |
| Password_2 | Number of Characters | The system must require a password contain at least 1 upper case, 1 lower case, 1 numerical, and 1 special character | 1.0 | 1.0 |
| Password_3 | Reuse of Passwords | The system must require a password must not be one of the last five (5) passwords already used | 1.0 | 1.0 |

## E.  PHR-A Module Content

The PHR-A implements a cohesive set of user functions loosely modeled around the following American Association of Diabetes Educators (AADE) recommended topic areas.

## Healthy Eating Module

The Healthy Eating Module provides users with several related tools aimed at monitoring food intake, providing feedback/advice, and helping users to anticipate the effects of certain foods ("What if I ate…" analysis).  The Healthy Eating Module's focus is eating a balanced diet of the right food groups (not about calorie and/or carbohydrate intake per se). Tracking nutrition intake will utilize a diabetes food pyramid methodology whereby the user will track data based on the number of servings they eat from each category, such as starches, protein, fruits, vegetables, or high fat or sweet foods.  Feedback will be based on the user's eating behavior relative to the pyramid guidelines. Feedback will include information related to diabetes and healthy eating habits.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|--------|------------------|-------------|----------|-----------|
| HealthyEating_1 | Nutrition Data Entry By Category | Allows user to enter number of servings for a nutrition category | 1.0 | 1.0 |
| HealthyEating_2 | Nutrition Time Data Entry By Category | Optionally, allows user to track the time they ate a meal/snack. | 1.0 | 1.0 |

| HealthyEating_3 | Daily Nutrition Feedback | Provides user feedback on their progress towards healthy eating for the day based on data entry and food pyramid guidelines. Feedback shall be textual and graphical | 1.0 | 1.0 |
|---|---|---|---|---|
| HealthyEating_4 | Weekly Nutrition Feedback | Provides user feedback on their progress toward healthy eating for the past seven days based on data entry and food pyramid guidelines. Feedback shall be textual and graphical | 1.0 | 1.0 |
| HealthyEating_5 | Personalized Food Pyramid | Allows user to personalize the daily required servings for each food pyramid category | 1.0 | 1.0 |
| HealthyEating_6 | Food Pyramid Reset | Allows user to reset food pyramid to recommended guidelines | 1.0 | 1.0 |
| HealthyEating_7 | Estimated Daily Nutrition Data Entry | Allows the user to quickly enter estimated future servings of food | 1.0 | 1.0 |
| HealthyEating_8 | Projected Daily Nutrition Feedback | Provides user feedback using actual and estimated food intake data verse daily goals to determine how best to meet their daily goal | 1.0 | 1.0 |
| HealthyEating_9 | Food Pyramid Information | Provide user with information about the nutritional categories. Information should include what food items belong in each category and sample serving size information for representative foods | 1.0 | 1.0 |
| HealthyEating_10 | Nutrition Information Links | Provider users with a list of additional external vetted sources (websites) of information about nutrition | 1.0 | 1.0 |

## Being Active Module

The Being Active Module provides users with several related tools aimed at improving their understanding and ability to improve their flexibility, strength, and cardiovascular fitness. Feedback will include diabetes specific information.

Once a month, the Being Active Module will include the Diabetes Activity Challenge. This is a brief activity that will ask the user to record their blood sugar before and after sustained physical activity.  The application will have specific graphs to show the correlation between the blood sugar levels before and after the activity demonstrating how activity can improve blood sugar control.

| Req ID | Requirement Name | Description | Vers New | Vers Upd. |
|---|---|---|---|---|
| BeingActive_1 | Activity Data Entry By Category | Allows user to enter number of minutes or duration spent based on category (flexibility, strength, or cardio) | 1.0 | 1.0 |
| BeingActive_2 | Activity Data Entry By Identified Activity | Allows user to enter number of minutes or duration spent engaged in a specific activity | 1.0 | 1.0 |
| BeingActive_3 | Activity Time Data Entry | Optionally allows user to enter start time of activity | 1.0 | 1.0 |
| BeingActive_4 | Activity Intensity Data Entry | Optionally allows user to specific the level of intensity for an activity | 1.0 | 1.0 |
| BeingActive_5 | Estimated Calories Burned Data Entry | Optionally allow user to enter calories burned during an activity | 1.0 | 1.0 |
| BeingActive_6 | MS Health Vault Link | If a link exists with Health Vault the system must have the capability to synchronize activity data | 1.0 | 1.0 |
| BeingActive_7 | Activity Feedback Based on Time | Provides users feedback on activity level trends, progress towards personalized activity goals based on time. Feedback shall be textual and graphical | 1.0 | 1.0 |
| BeingActive_8 | Activity Feedback Based on Calories Burned | Provide users feedback on activity level trends, progress towards personalized activity goals based on calories burned. Feedback shall be textual and graphical | 1.0 | 1.0 |
| BeingActive_9 | Estimated Activity Data Entry | Allows the user to quickly enter estimated activities | 1.0 | 1.0 |
| BeingActive_10 | Personalized Daily Goal Entry | Allows the user to enter daily goals for each category. Initial suggested goals will be based on standardized recommendations for activity (i.e. 1 hour of cardio per day) | 1.0 | 1.0 |
| BeingActive_11 | Personalized Weekly Goal Entry | Allows the user to enter weekly goals for each category. Initial suggested goals will be based on standardized recommendations for activity (i.e. 3 hours of strength training per week) | 1.0 | 1.0 |
| BeingActive_12 | Activity Goal Reset | Allows the user to reset their goals based on standards | 1.0 | 1.0 |
| BeingActive_13 | Projected Daily Activity Feedback | Provides user feedback using actual and estimated activity data verse daily goals to determine how best to meet their daily goal | 1.0 | 1.0 |
| BeingActive_14 | Projected Weekly Activity Feedback | Provides user feedback using actual and estimated activity data verse weekly goals to determine how best to meet their weekly goals | 1.0 | 1.0 |
| BeingActive_15 | Activity Information | Provide user with information about the categories of activity. Information should include what activities belong in each category | 1.0 | 1.0 |
| BeingActive_16 | Activity Information Links | Provider users with a list of additional external vetted sources (websites) of information about activity | 1.0 | 1.0 |

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| BeingActive_17 | Diabetes Activity Challenge Notification | Notify user of Diabetes Activity Challenge | 1.0 | 1.0 |
| BeingActive_18 | Diabetes Challenge Feedback | Provide user specific feedback related to the Challenge include data (textual/graphical) based on blood glucose levels before and after an activity | 1.0 | 1.0 |

## Taking Medications Module

The Taking Medications Module provides users with a detailed medication reminder / compliance tracker and, if applicable, a meal-time insulin dosage calculator and a supplemental bolus insulin estimator.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| Medications_1 | Scheduled Medication Reminder | Based on a user configured medication schedule the system shall generate a reminder for each medication dose. Based on delivery mechanism, the content of the reminder will differ | 1.0 | 1.0 |
| Medications_2 | Email Medication Reminder | The reminder shall include the time the drug is supposed to be taken, name of the medication, the dosage, an image of the medication; dosage; link to externally maintained medication reference materials; a link to a web page allowing the user to indicate if/when the dosage was actually taken, to close reminder and not track compliance, or to remind again in X minutes | 1.0 | 1.0 |
| Medications_3 | Text Message Reminder | The reminder shall include the name of the drug, the dosage, and the time the drug should be taken | 1.0 | 1.0 |
| Medciations_4 | Gadget or Website Reminder | The reminder shall include the time the drug is supposed to be taken, name of the medication, the dosage, an image of the medication; dosage; link to externally maintained medication reference materials; a link to a web page allowing the user to indicate if/when the dosage was actually taken, to close reminder and not track compliance, or to remind again in X minutes | 1.0 | 1.0 |
| Medications_5 | Medication Regimen Setup | The system shall provide the user with a method for inputting and managing their medication regimen including medication name, dosage, and schedule.  Medicine selection shall include a method for users to visually confirm that the automatically selected image matches the actual medication on hand | 1.0 | 1.0 |
| Medications_6 | Medication Reminder Preferences | The system shall provide users the ability to manage all preferences related to Medication Reminders such as reminder timing (ex. 10 minutes before scheduled time); reminder blackout periods (ex. 11pm – 5am); reminder | 1.0 | 1.0 |

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| | | automatic closing (ex. 2 days past due); delivery mechanism (ex. Web-based, text message, or email) | | |
| Medications_7 | Mealtime Bolus Insulin Estimator | The system shall provide users with a specific insulin units recommendation and carb to insulin ratio data based on user entered/specific carbohydrate to insulin ratio and planned carbohydrate consumption | 1.0 | 1.0 |
| Medications_8 | Supplemental Bolus Insulin Estimator | The system shall provide users with a specific insulin units recommendation and insulin sensitivity factor  data based on manual entry of their current blood glucose level, total daily insulin requirement, ideal blood glucose, and selected rule (1500 or 1800) | 1.0 | 1.0 |

Reducing Risks focuses on standards of care including appropriate lab testing and examinations.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| ReducingRisk_1 | Microsoft Health Vault | The system shall synchronize A1c and cholesterol lab data and appointment information with Health Vault | 1.0 | 1.0 |
| ReducingRisk_2 | Lab Data Entry | The system shall allow the user to enter A1c and cholesterol lab data including lab test date and value | 1.0 | 1.0 |
| ReducingRisk_3 | Exam Data Entry | The system shall allow the user to past examination data for primary care, podiatry, and eye exams including data and type of exam | 1.0 | 1.0 |
| ReducingRisk_4 | Appointment Data Entry | The system shall allow the user to enter future appointment data including type of appointment (dr. visit or lab test), date/time, location, who with, and contact information | 1.0 | 1.0 |
| ReducingRisk_5 | Appointment Maintenance | The system shall allow the user to modify the appointment information. They shall be allowed to mark it kept | 1.0 | 1.0 |
| ReducingRisk_6 | Appointment Reminder Configuration | The system shall allow the user to configure how they are reminded of appointments. Options include text message, email, or website usage | 1.0 | 1.0 |
| ReducingRisk_7 | Appointment Reminder Action | The system shall allow the user to close a reminder, mark the appointment as kept, or remind again in X time | 1.0 | 1.0 |
| ReducingRisk_8 | Appointment Reminder Delivery | The system shall send appointment reminders based on the user's preference | 1.0 | 1.0 |
| ReducingRisk_9 | Lab Testing Reminder | The system shall reminder the patient about the need to get lab tests based on data enter and standard lab testing schedules | 1.0 | 1.0 |
| ReducingRisk_10 | Lab Testing Reminder Email Message | The lab test reminder will contain information about which lab test is required, when the last | 1.0 | 1.0 |

| REQ ID | REQUIREMENT NAME | DESCRIPTION | | |
|---|---|---|---|---|
| | | one was performed, and information about why it is important | | |
| ReducingRisk_11 | Lab Testing Reminder Text Message | The lab test reminder will state the lab test that is required and date of last lab test | 1.0 | 1.0 |
| ReducingRisk_12 | Appointment Reminder Text Message | The system shall send the user a text message reminder about their next appointment including the appointment date/time and who it is with | 1.0 | 1.0 |
| ReducingRisk_13 | Appointment Reminder Email Message | The system shall send the user an email reminder about their next appointment including the appointment date/time, type, who it is with, contact information, and a link to a take an action on the appointment | 1.0 | 1.0 |
| Reducingisk_14 | Gadget or Website Reminder | The system shall provide functionality to reminder the user of appointments and lab tests | 1.0 | 1.0 |

## Monitoring – Blood Sugar

Monitoring focuses on improving a patient's well-being through proper blood sugar monitoring.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| MonitoringBG_1 | Microsoft HealthVault | The system shall synchronize blood sugar data with Microsoft HealthVault | 1.0 | 1.0 |
| MonitoringBG_2 | Blood Sugar Data Entry | The system must allow the user to enter blood sugar information including date/time of reading and result. | 1.0 | 1.0 |
| MonitoringBG_3 | Blood Sugar Time Period Maintenance | The system must allow the user to specify what times each time period (before/after breakfast, etc) falls into. | 1.0 | 1.0 |
| MonitoringBG_4 | Blood Sugar Range Maintenance | The system must allow the user to specify high/low values according to time periods for blood sugar readings. | 1.0 | 1.0 |
| MonitoringBG_5 | Blood Sugar Log Book | The system must display blood sugar information in a standard log book format broken down by time period including total readings per time period/day and average values per time period/day. The data should be colored and use different shapes according to high/low specifications. Normal values should be black circles, low values blue diamonds, and high values red blocks. | 1.0 | 1.0 |
| MonitoringBG_6 | Blood Sugar Trending Graph | The system must display a blood sugar trending graph for a specified number of days. | 1.0 | 1.0 |
| MonitoringBG_7 | Blood Sugar Log Book and Graph Time Range Selection | The system must default to the last seven days when displaying the log book or graphs. The system must allow the user to specify a custom date range or quickly select last seven days, last week, last two week, last month or last three months. | 1.0 | 1.0 |
| MonitoringBG_8 | Blood Sugar Graph | The system must optionally allow the user to | 1.0 | 1.0 |

| | Options | display additional information on the graphs including medication taken information, mood data, activity data, and nutrition information | | |
|---|---|---|---|---|

## Monitoring -- Weight

Monitoring also focuses on improving a patient's well-being through proper weight management. The PHR-A's approach to weight management emphases a balanced approach incorporating concepts of health eating and being active.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| MonitoringWeight_1 | Microsoft HealthVault | The system shall synchronize weight data with Microsoft HealthVault | 1.0 | 1.0 |
| MonitoringWeight_1 | Weight Data Entry | The system must allow the user to enter weight information including date/time of reading and the weight in pounds | 1.0 | 1.0 |
| MonitoringWeight_1 | Weight Trending Graph | The system must display a weight trending graph for a specified number of days | 1.0 | 1.0 |
| MonitoringWeight_1 | Weight Graph Time Range Selection | The system must default to the last seven days when displaying graph. The system must allow the user to specify a custom date range or quickly select last seven days, last week, last two week, last month or last three months | 1.0 | 1.0 |

## Outlook

The Outlook Module administers pre-configured surveys on a monthly basis with feedback to the user on both.

| Coping_1 | Questionnaire Presentation | The system shall present users with brief questionnaires based on a pre-determined schedule, user preferences and/or responses to daily mood updates | 1.0 | 1.0 |
|---|---|---|---|---|
| Coping_2 | Automated Feedback | The system shall automatically review questionnaire data in conjunction with other user data points to make specific suggestions for ways the user might resolve current issues or better cope with a their specific situation | 1.0 | 1.0 |

## F.  Tips

The PHR-A shall provide users with the ability to subscribe to tip topic areas and types as well as their preferred time to receive tips and mode of tip delivery (e.g., within gadget, email, text message). The tips are organized around the aforementioned AADE categories.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| TipOptions_1 | User Tip Maintenance | The system must allow users to subscribe to different tip topic areas and types | 1.0 | 1.0 |

| TipOptions_2 | User Tip Opt Out | The system must allow users a mechanism to unsubscribe from future tips upon receipt of a tip. The user must be presented with options to unsubscribe from either the individual tip topic area or all future tips | 1.0 | 1.0 |
|---|---|---|---|---|
| TipOptions_3 | User Tip Schedule | The system must allow users the ability to set preferences for what time and how often the system distributes their tips | 1.0 | 1.0 |
| TipOptions_4 | User Tip Delivery Mechanism | The system must allow users the ability to set how tips are delivered. Options are email, text message, or gadget/website | 1.0 | 1.0 |

## G. External Systems Interfaces

The following external system interfaces will need to be defined to interface with the Host System:

- Microsoft HealthVault

## END OF EXCERPT FROM FUNCTIONAL REQUIREMENTS DOCUMENT

### *TASK 2: Finalize Version 1 of the Application – COMPLETE*

This task is complete. The next set of pages illustrates key aspects of Version 1. Note that certain features of Version 1 are now obsolete due to changes that resulted from later tasks in the project. We provide screen shots of Version 2 later in this document.

## Domain Diagram

**Account Setup / Maintenance**

Create Account / Update Security Settings

Set Start Date & Feedback Day

Populate Demographics

Populate Medications

Set System Defaults & Messaging Options

Set Default Time Periods

**Daily**

Add Food

Add Physical Activity

Add Medication Compliance

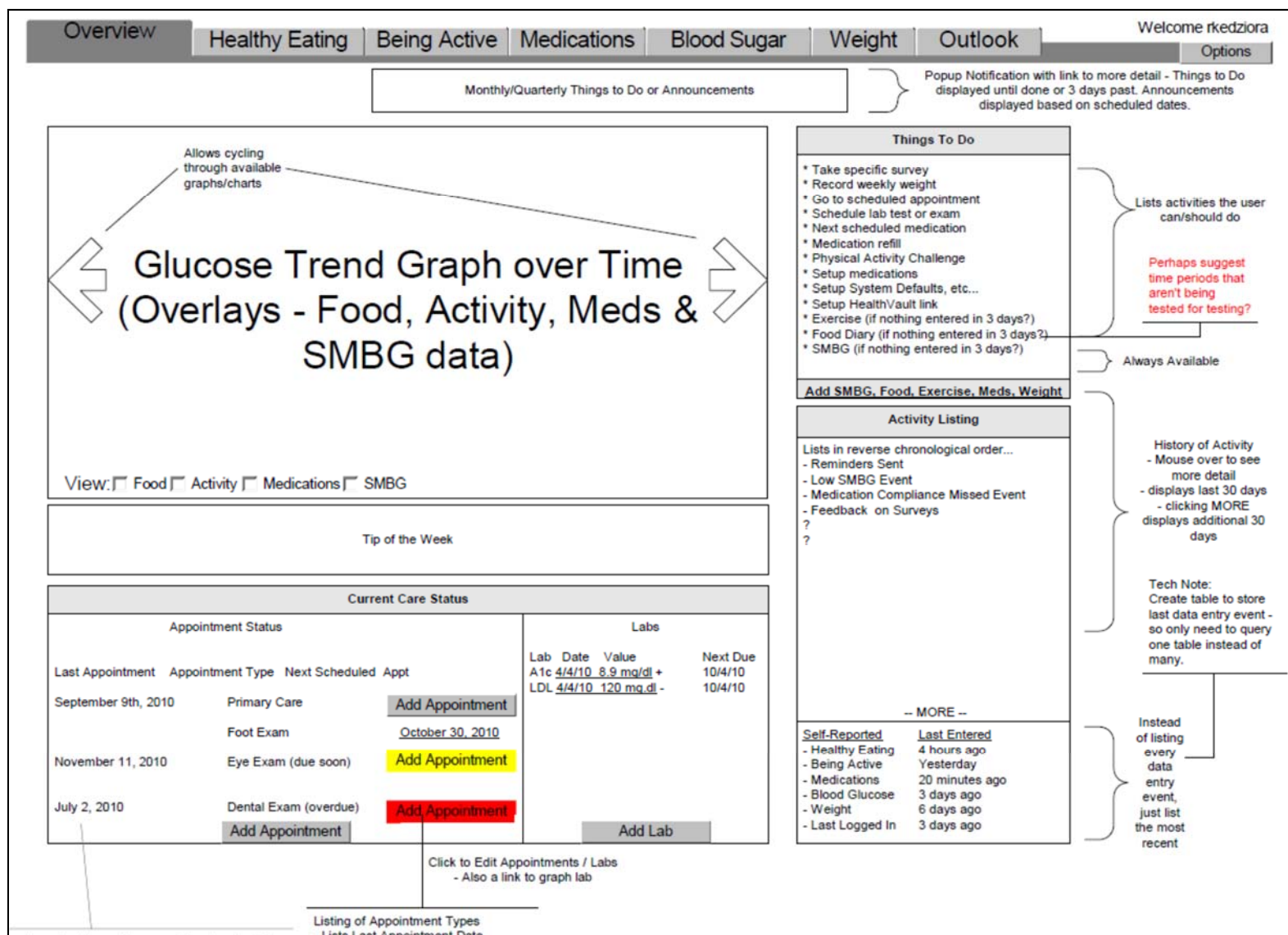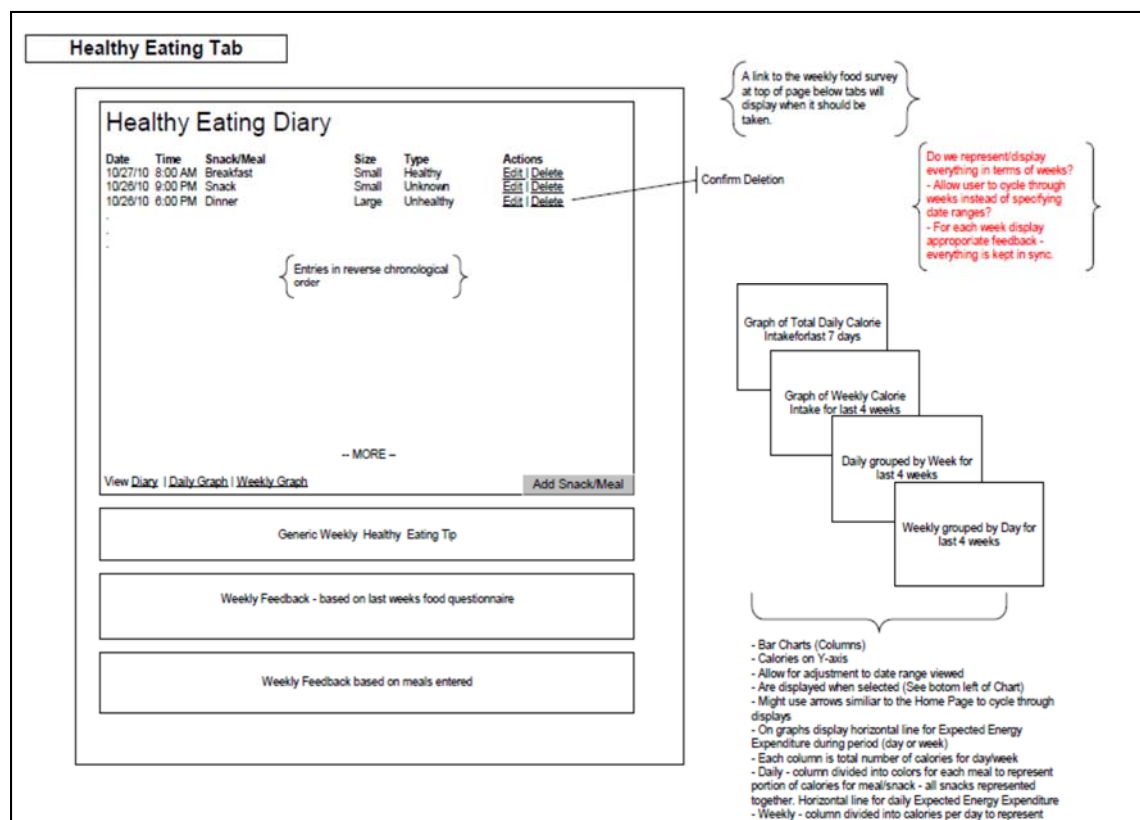Add SMBG Data

Add Weight

Add Lab Test Results

Add Appointments

Reminders
- Schedule lab test and appointments
- Appointment reminders

**Weekly**

Weekly Food Survey

Feedback

Weekly Activity Survey

Feedback

Weight Maintenance Feedback

Tips

Data Entry Reminders

**Monthly**

Medication Reconciliation Reminder

Monthly Surveys (Schedule below)

Feedback

**Quarterly**

Physical Activity Challenge

Reminder
- Time to adjust PAR?

**Miscellanous Pages to Produce**

Marketing / Intro Material

Terms & Conditions

Medical Disclaimer

Privacy Statement

FAQ

About Us

**Background Material**

Meal Size and Healthy Eating Help

Physical Activity Challenge Content

Level of Exertion Help

Physical Activity Examples for different types

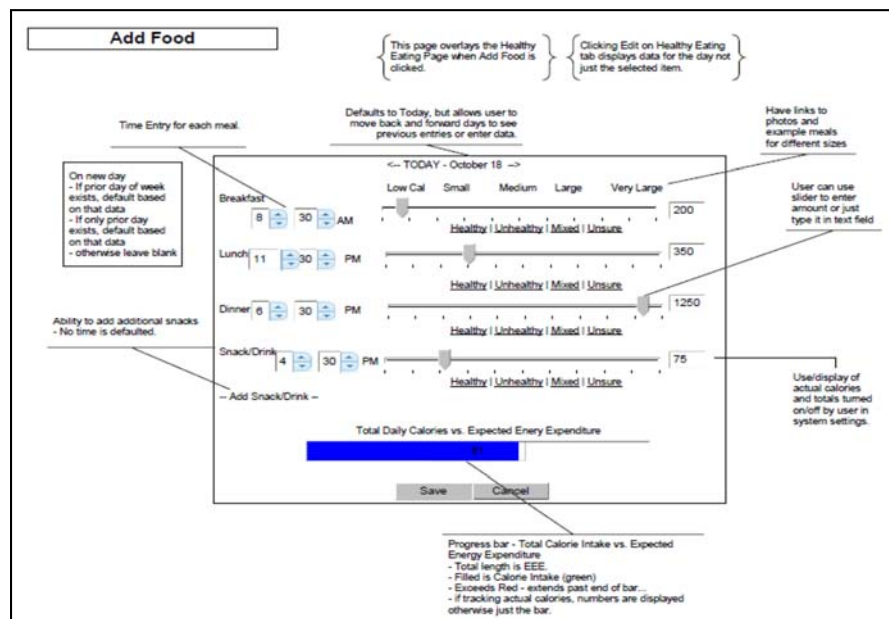| Month 1 | Month 2 | Month 3 | Month 4 --> |
|---------|---------|---------|-------------|
| Brief Illness Perception Questionnaire (B-IPQ) | Centers for Epidemiologic Studies - Depression (CESD) | Diabetes Distress Screener | Environmental Barriers to Adherence - 4 domains |
| Feedback | Feedback | Feedback | Feedback |

Medication, exercising, testing SMBG, eating

The Domain Diagram above indicates the time at which various events in the PHRA occur. For example, account set-up occurs once, and then the user can maintain/update information within this domain as needed. The entering of information pertaining to eating, physical activity, medications, etc. occurs daily. Surveys important for feedback on physical activity and healthy eating, however, take place once a week. Certain challenges built into Version 1 (and 2) occur monthly, so as to keep the user engaged. The project still needs to create disclaimer pages necessary for public distribution.

Overview | Healthy Eating | Being Active | Medications | Blood Sugar | Weight | Outlook

Welcome rkedziora
Options

Monthly/Quarterly Things to Do or Announcements

Popup Notification with link to more detail - Things to Do displayed until done or 3 days past. Announcements displayed based on scheduled dates.

Allows cycling through available graphs/charts

Glucose Trend Graph over Time (Overlays - Food, Activity, Meds & SMBG data)

View: ☐ Food ☐ Activity ☐ Medications ☐ SMBG

Tip of the Week

**Things To Do**

* Take specific survey
* Record weekly weight
* Go to scheduled appointment
* Schedule lab test or exam
* Next scheduled medication
* Medication refill
* Physical Activity Challenge
* Setup medications
* Setup System Defaults, etc...
* Setup HealthVault link
* Exercise (if nothing entered in 3 days?)
* Food Diary (if nothing entered in 3 days?)
* SMBG (if nothing entered in 3 days?)

Lists activities the user can/should do

Perhaps suggest time periods that aren't being tested for testing?

Always Available

**Add SMBG, Food, Exercise, Meds, Weight**

**Activity Listing**

Lists in reverse chronological order...
- Reminders Sent
- Low SMBG Event
- Medication Compliance Missed Event
- Feedback on Surveys
?
?

History of Activity
- Mouse over to see more detail
- displays last 30 days
- clicking MORE displays additional 30 days

Tech Note:
Create table to store last data entry event - so only need to query one table instead of many.

-- MORE --

| Self-Reported | Last Entered |
|---|---|
| - Healthy Eating | 4 hours ago |
| - Being Active | Yesterday |
| - Medications | 20 minutes ago |
| - Blood Glucose | 3 days ago |
| - Weight | 6 days ago |
| - Last Logged In | 3 days ago |

Instead of listing every data entry event, just list the most recent

**Current Care Status**

Appointment Status

| Last Appointment | Appointment Type | Next Scheduled Appt |
|---|---|---|
| September 9th, 2010 | Primary Care | Add Appointment |
| | Foot Exam | October 30, 2010 |
| November 11, 2010 | Eye Exam (due soon) | Add Appointment |
| July 2, 2010 | Dental Exam (overdue) | Add Appointment |
| Add Appointment | | |

Labs

| Lab | Date | Value | Next Due |
|---|---|---|---|
| A1c | 4/4/10 | 8.9 mg/dl + | 10/4/10 |
| LDL | 4/4/10 | 120 mg.dl - | 10/4/10 |

Add Lab

Click to Edit Appointments / Labs
- Also a link to graph lab

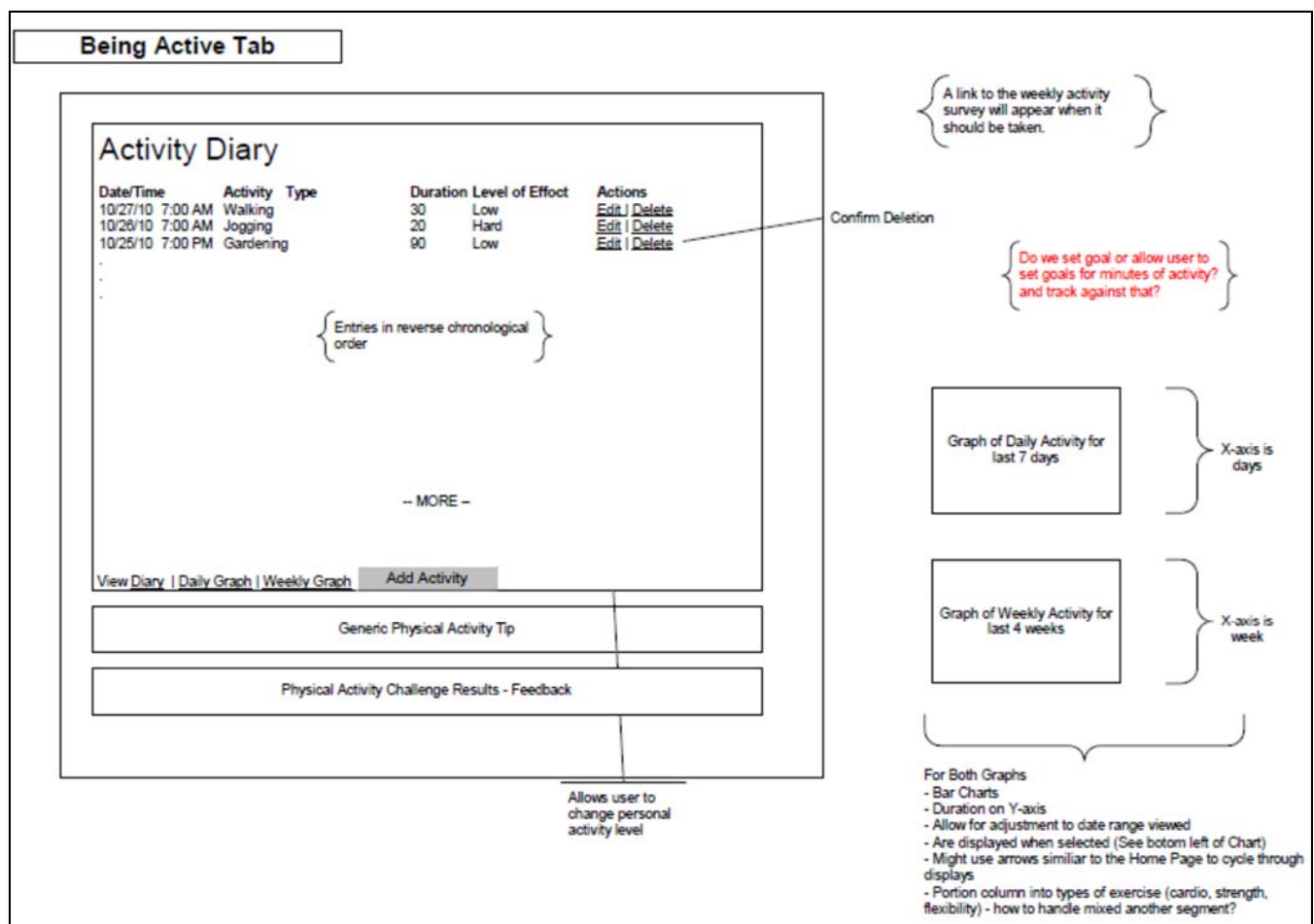Listing of Appointment Types
- Lists Last Appointment Date

The above diagram from Version 1 shows the first page that the user (already registered) sees when logging into the application. This page or tab covers those activities considered part of 'reducing risks' (labs, appointments) as well as summary data on things to do and events within over tabs. It also displays results from monitoring -- in graphical format -- that the user can scroll through.

**Healthy Eating Diary**

| Date | Time | Snack/Meal | Size | Type | Actions |
|---|---|---|---|---|---|
| 10/27/10 | 8:00 AM | Breakfast | Small | Healthy | Edit | Delete |
| 10/26/10 | 9:00 PM | Snack | Small | Unknown | Edit | Delete |
| 10/26/10 | 6:00 PM | Dinner | Large | Unhealthy | Edit | Delete |

Entries in reverse chronological order

-- MORE --

View Diary | Daily Graph | Weekly Graph     Add Snack/Meal

Generic Weekly Healthy Eating Tip

Weekly Feedback - based on last weeks food questionnaire

Weekly Feedback based on meals entered

A link to the weekly food survey at top of page below tabs will display when it should be taken.

Confirm Deletion

Do we represent/display everything in terms of weeks?
- Allow user to cycle through weeks instead of specifying date ranges?
- For each week display appropriate feedback - everything is kept in sync.

Graph of Total Daily Calorie Intake for last 7 days

Graph of Weekly Calorie Intake for last 4 weeks

Daily grouped by Week for last 4 weeks

Weekly grouped by Day for last 4 weeks

- Bar Charts (Columns)
- Calories on Y-axis
- Allow for adjustment to date range viewed
- Are displayed when selected (See bottom left of Chart)
- Might use arrows similiar to the Home Page to cycle through displays
- On graphs display horizontal line for Expected Energy Expenditure during period (day or week)
- Each column is total number of calories for day/week
- Daily - column divided into colors for each meal to represent portion of calories for meal/snack - all snacks represented together. Horizontal line for daily Expected Energy Expenditure
- Weekly - column divided into calories per day to represent

The Healthy Eating (above) and Add Food (below) graphics show the main features of this tab or domain within the PHRA. Note that with construction of Version 1, the emphasis on the Food Pyramid given in the Functional Requirements changed to a much simpler format. This change was driven by expert feedback.

**Add Food**

This page overlays the Healthy Eating Page when Add Food is clicked.

Clicking Edit on Healthy Eating tab displays data for the day not just the selected item.

Time Entry for each meal.

Defaults to Today, but allows user to move back and forward days to see previous entries or enter data.

Have links to photos and example meals for different sizes

<-- TODAY - October 18 -->

On new day
- If prior day of week exists, default based on that data
- If only prior day exists, default based on that data
- otherwise leave blank

Breakfast 8 : 30 AM    Low Cal  Small  Medium  Large  Very Large   200
Healthy | Unhealthy | Mixed | Unsure

Lunch 11 : 30 PM    350
Healthy | Unhealthy | Mixed | Unsure

Dinner 6 : 30 PM    1250
Healthy | Unhealthy | Mixed | Unsure

Snack/Drink 4 : 30 PM    75
Healthy | Unhealthy | Mixed | Unsure

-- Add Snack/Drink --

User can use slider to enter amount or just type it in text field

Use/display of actual calories and totals turned on/off by user in system settings.

Ability to add additional snacks
- No time is defaulted.

Total Daily Calories vs. Expected Enery Expenditure

Save    Cancel

Progress bar - Total Calorie Intake vs. Expected Energy Expenditure
- Total length is EEE.
- Filled is Calorie Intake (green)
- Exceeds Red - extends past end of bar...
- if tracking actual calories, numbers are displayed otherwise just the bar.

**Being Active Tab** — Activity Diary mockup with annotations.

The Being Active (above) and Add Activity (below) graphics depict the major features of the Being Active tab, which allows user to track physical activity, receive specific feedback, and review generic tips. As with Healthy Eating and compared with the Functional Requirements document, the input of physical activity was simplified in the construction of Version 1 in response to expert feedback.



**Add Activity** — mockup with annotations.

## Medication Tab

Displays indicator (take with food/water) based on input and doctor's orders.

Click Taken to indicate the medication has been administered. No further action necessary unless insulin. User prompted to enter dosage.

**Current Medication List**

☐ View Past Medications

| Medication | Last Time Taken | Next Scheduled | Next Refill Date | |
|---|---|---|---|---|
| Metformin 500mg Daily | Yesterday, 8am | Overdue | Yesterday | Taken \| Edit Medication \| Remove |
| Acarbose 25mg Three Times Day | Yesterday, 5pm | Today 12pm | November 15 | Taken \| Edit Medication \| Remove |

Need option for NO MEDICATIONS

Add Medication

Edit Medication allows altering the prescription or schedule.

Medication Compliance Chart

Chart - Listing of medication and when taken over days (like SMBG chart)

Selecting View Past Medications changes title and displays complete history...

Generic Weekly Medication Tip

Wizard style panel displays to allow user to enter when they will take medications.

**Add Medication**

Medication  [ ▾ ]
Dosage  [ ▾ ]
Frequency  [ ▾ ]
Prescription Date  [ ]
Days Supply  [ ]
Next Refill Date  [ ]
Notes  [ ]

Next Refill Date will autopopulate based on prescription date and days supply

Select icons based on doctor's orders

User selects icons to display with med based on DR. orders

Save    Cancel

**Medication Schedule Wizard**

1. Do you take the medication daily?
1a. Do you take the medication more than once per day?
1b. Enter the times of day you want to take your medication?

2. Do you take the medication weekly?
2a. What day do you take the medication?
2b. Enter the time of day you want to take your medication?

---

The medication tab, shown at the left, is the aspect of the PHRA that allows users to track their medications – what they are taking and if they took it. They can also receive tips/reminders on medication, and can link out to education on particular medications so that they can better understand a medication's actions.

This tab does not suggest any adjustments to medications.

Also, while other medications are indeed important for diabetes management, at this time we are addressing only diabetes medications.

Previously we had an insulin dose calculator for people taking meal-time insulin, but the feedback we received led us to omit that functionality.

**Blood Sugar Tab**

Glucose Trend Graph over time
(Overlays - Food, Activity, Meds & SMBG data)
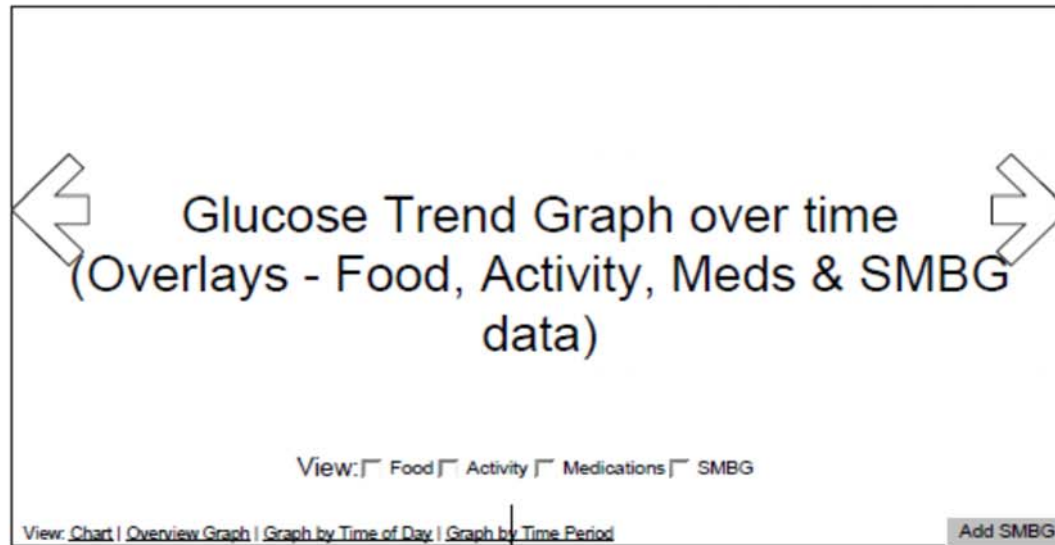
Clicking arrows displays other graphs/charts

View: ☐ Food ☐ Activity ☐ Medications ☐ SMBG

View: Chart | Overview Graph | Graph by Time of Day | Graph by Time Period

Add SMBG

Clicking options changes display

Checking options displays data overlaid on graph of SMBG

Overlay - displayed when Add SMBG is clicked

Displays UOM based on system parameter

**Add SMBG Panel**

Date: _____    Reading: _____ mg/dl

Time: _____    Period: _____ ⌄

Notes: _____

Save    Cancel

Glucose Chart

SMBG Graph
(Glucose by Time of Day)

SMBG Graph
(Pie Charts by Time Period)
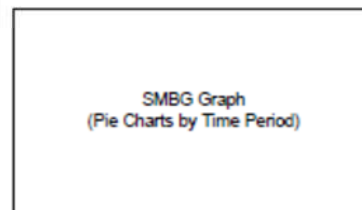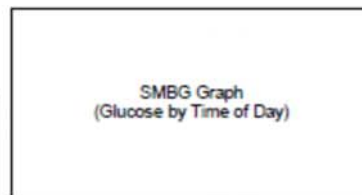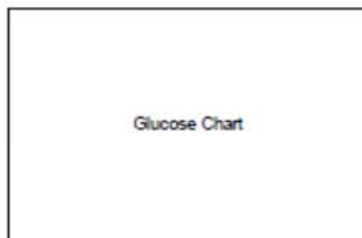
Similiar to CDMP

This graphic displays Version 1 features for monitoring blood sugar, and the graphic on the following page displays Version 1 features for monitoring weight. Both are part of the "monitoring" concept overall. The PHRA does not provide weight loss feedback until after the user has done weight monitoring consistently for 6 weeks.

**Weight Tab**

Weight Graph
(x-axis - dates - auto adjust to data
y-axis - pounds / kilograms based on settings)

View Chart | Graph                                    Add Weight

Weight Tip or How to weigh yourself properly?

← Last weeks weight feedback →

Need rules on what is
insufficient data for
calculating feedback.
Need rules to compute
feedback when
insufficient data is
present

Overlay -
displayed when
Add Weight is
clicked

Add Weight
Date:              Weight:        lbs
Notes:

Save    Cancel

Uses User
Default Unit of
Measure

- Always store as
pounds

Display feedback
from past weeks -
arrows allow
moving
backwards an d
forward to other
week.s

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## Outlook Tab

### Surveys

* Weekly Food Survey
* Weekly Exercise Survey
* Brief Illness Perception
* CESD
* Diabetes Distress Screener
* Environmental Barriers (Medication)
* Environmental Barriers (Exercising)
* Environmental Barriers (Testing SMBG)
* Environmental Barriers (Eating)

Lists All Surveys

### Survey History

* Weekly Food Survey (October 4)
* Weekly Exercise Survey (October 4)
* Brief Illness Perception (September 15th)
* Environmental Barriers (Eating) (September 3)

Entries in reverse chronological order

Lists Surveys Taken

What is the copyright on these surveys? Do we have any issues?
- We need permission for B-IPQ lizbroadbent@clear.net.nz

### Disclaimer and Our Views on Psychological Testing

Our surveys are intended to be fun and educational, and they may help increase your awareness of particular experiences or of particular forms of psychological distress. They are not by themselves tools for diagnosing any type of health or mental health condition.

Psychological tests and surveys should not be understood as providing any type of diagnosis or healthcare recommendation.

In the view of this site, self-administered psychological screening tests may help to enhance self-awareness of one's own experiences, but cannot give any well-informed recommendation about what should be done about those experiences. In other words, by asking about particular experiences, a psychological test may simply help highlight elements of those experiences. Having those experiences highlighted may offer an individual an opportunity to reflect on them at greater length, or to consider their relevance in a broader life context. What an individual chooses to do – or 'should' choose to do -- with the results of any given test, is a matter for the individual and should not be dictated by the test itself.

CONTENT FROM: CounsellingResource.com

## DISCLAIMER

Survey are taken or displayed with feedback here.

Always consult with a trained mental health professional if you are experiencing depressive feelings and/or difficulties in your daily functioning that cause you anxiety or worry.

This test is meant to be used as a starting point, not as a diagnosis tool. This score

Displays after survey is taken

In Version 1, the Outlook tab (shown here) had gaps. The feedback we received said that we needed to add more content on the rationale for users to complete surveys about their outlook, and that certain surveys did not belong in this section at all. The feedback that the PHRA itself gave to users was insufficient. Hence, this section has changed.

**User Setup / Configuration - Security Tab**

Security | Demographics | System Settings | Defau

Username: mjordan

Primary Email:

Secondary Email:

Password:

Confirm Password:

Security Question:

Other:

Security Answer:

Save | Cancel

Standard Set of Security Question.

If user selects "Other" as Security Question - this box is activated allowing the user to enter their own question.

The next set of graphics show the sections of Version 1 that allow the user to configure the PHRA to their needs and preferences. They can return to this section at any time.



**User Setup / Configuration - Demographics Tab**

Date of Birth: mm/dd/yyyy

Height _____ inches _____ centimeters

Starting Weight _____ pounds _____ kilograms

Gender ● Male ○ Female

Personal Activity Level: _____ ?

Cell Phone Number ( ) -

Carrier: _____

Zip Code: _____

Save | Cancel

Always save as inches

Automatically update both fields when user changes one of them.

Always store as pounds.

Help Link to display details on meaning of the different levels of personal activity

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## User Setup / Configuration - System Settings

Default Blood Sugar Units  ○ mg/dl  ○ mmol  Days of the week

Weight  ○ pounds  ○ kilograms

Will turn on/off ability to actually enter a number.

Start week on : [         ▼]

Do you want to track actual calories consumed?  ● Yes  ○ No

Do you want to track actual calories burned?  ● Yes  ○ No

Usual warning message...

Do you want to receive email reminders?  ● Yes  ○ No

Do you want to receive text messages?  ● Yes  ○ No

Normal rates apply.

| | | | | | |
|---|---|---|---|---|---|
| Appointments | ● Yes | ○ No | Appointments | ● Yes | ○ No |
| Labs | ● Yes | ○ No | Labs | ● Yes | ○ No |
| Medication Refills | ● Yes | ○ No | Medication Refills | ● Yes | ○ No |
| Take Medication | ● Yes | ○ No | Take Medication | ● Yes | ○ No |
| Surveys | ● Yes | ○ No | Surveys | ● Yes | ○ No |

Only active if user wants to receive messages

Do you want to limit the time when emails are sent?  ● Yes  ○ No

No emails between the following hours:  [11] [30] PM

[7] [30] AM

Do you want to limit the time when text messages are sent?  ● Yes  ○ No

No text messages between the following hours:  [11] [30] PM

[7] [30] AM

Only active if user wants to block sending emails.

[ Save ]  [ Cancel ]

---

## User Setup / Configuration - Default Time Periods

| Time Period | From Time | | | Until Time | Glucose Lower Limit | Glucose Upper Limit |
|---|---|---|---|---|---|---|
| AllDay | | | | | 80 | 120 |
| Before Breakfast | 7 ▼ | 00 ▼ | AM ▼ | 09:00 AM | 80 | 120 |
| After Breakfast | 9 ▼ | 00 ▼ | AM ▼ | 11:30 AM | 80 | 120 |
| Before Lunch | 11 ▼ | 30 ▼ | AM ▼ | 12:30 PM | 80 | 120 |
| After Lunch | 12 ▼ | 30 ▼ | PM ▼ | 03:00 PM | 80 | 120 |
| Before Dinner | 3 ▼ | 00 ▼ | PM ▼ | 06:00 PM | 80 | 120 |
| After Dinner | 6 ▼ | 00 ▼ | PM ▼ | 09:00 PM | 80 | 120 |
| Bed Time | 9 ▼ | 00 ▼ | PM ▼ | 11:00 PM | 80 | 120 |
| Night | 11 ▼ | 00 ▼ | PM ▼ | 07:00 AM | 80 | 120 |

[ Save ]  [ Cancel ]

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myCareVention

Graph / Chart

View

Add

Edit
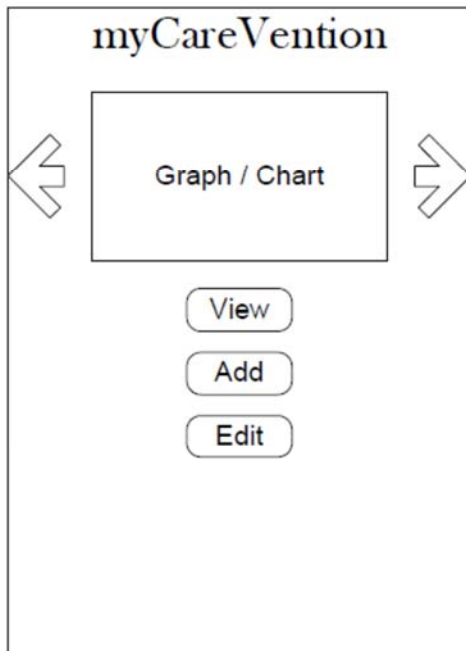
**Mobile Application notes**
- Top portion displays graph/chart - will be a static graphic (most mobile phones cannot handle flash graphics, which are used on the website.)
- Arrows allow user to cycle through the available charts (SMBG graph and charts, Weight, Labs, Meds, etc...)
- Clicking on View, Add or Edit displays a listing of items that can be acted upon. (See Next Page.)

Note: The PHRA is not a stand-alone application that can be downloaded from a smartphone's 'marketplace. It is accessible via a smartphone browser – different format than the Version seen from a computer.

myCareVention

Back

Food

Activity

Blood Sugar

Weight

Appointment

Lab

Medication

- Clicking on the item takes you to a page that performs the previously selected action (view, edit, add).

- View displays listing of items similiar to diary listing in reverse chronological order

- Edit displays listing of items, but allows user to select them for editing.

- Once the user is on the View/Add/Edit or deeper pages a Back button is displayed.

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### Task 3. Develop protocol and obtain approval from all appropriate Institutional Review Boards for User Testing of Version 1 -- COMPLETE

As mentioned in the Quarterly Report, for Task 3 we consulted with local and federal human subjects protection review experts. At that time, we learned that we did not need a formal protocol for the type of user input we are seeking, and because of the manner in which we are seeking it. The reason for this was because a) we were not formerly recruiting, b) we were not conducting "research" in the way it is defined, and c) when we received input from potential users, we did not collect any personal information from them. Indeed, the local IRB would not review a protocol that did not qualify as "research." We instead were instead working with potential users as we would with any subject matter experts.

Using the Diabetes Institute's quarterly publication of "In Control", we circulated the aforementioned diabetes tips for review by content experts and people with diabetes (over 6,000 people receive this publication). We have also provided guided demonstrations of the web site to Primary Care Physicians who work with people with diabetes and obtained their feedback.

We also presented a component of this work at the Annual Meeting of the Diabetes Technology Society (November) and received useful feedback from diabetes technology experts (chiefly scientists, engineers, programmers, and social scientists). Their main criticism was that we make sure users are informed that the "decision support" the PHR-A gives them could (although not necessarily) contain errors just because it contains thousands of lines of computer code. As such, everything the PHR-A tells the user must include that disclaimer and urge them to use their own common sense as well. Further, the comments focused on the low literacy and numeracy levels of the U.S. population (as indicated by research presented at the same panel) and the need to insure that the PHR-A is "pitched" toward those low levels so as to make it as accessible as possible to a wide variety of people.

We have been incorporating these and other suggestions. We changed the name of the application as part of these changes – Tracking My Diabetes.


### TASK 4. Test Version 1 of the Application, incorporate user feedback, and finalize a Version 2 –COMPLETE


***Due to the cessation of TRUE Research Foundation activities 1 April 2011, and the ensuing 4-month hiatus in the life course of the project, completion of this task was delayed.*** However, we have now completed this task. The next series of pages shows what Version 2 looks like. To see the 'live' application, register at: **http://www.trackingmydiabetes.com/**.

The following gives instructions for getting into and using the application.

Create an account.  You will select a user name and password.  An email message will be sent to you, to confirm and initiate the account.

Once you have an account, enter your name and password and log in.Logging in  will open to the Overview page.

3. Before leaving the home page and/or logging in, you can click each of the images to learn more about the different components of effective diabetes self management.

For example, selecting Healthy Eating opens a text box that tells you what you can expect to find about the effect of certain foods on blood sugar, portion sizes, and healthy food choices.



After creating an account and gaining access to TMD, you will be asked for some basic information about you to get your started. TMD functions best with as much information as possible about you, but you can get started by entering very little at first and completing your profile as you go. Mousing over the question mark for activity level will explain what is meant by the various options.
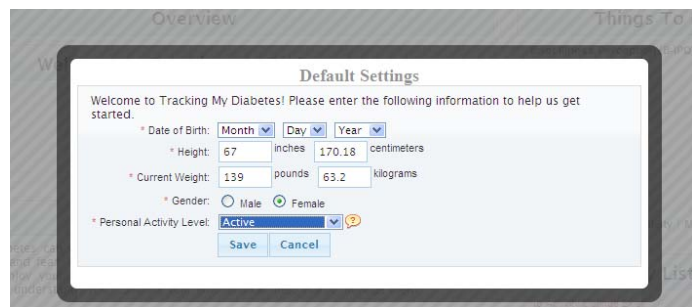


After logging in, you will be at the overview page. See screen shot below. The overview page covers the 'meta' data of the application – listing the things you are due to do, the things you have done, and upcoming medical appointments. It also includes a rotating tip of the week, selected at random from the sub-categories of diabetes self-management. If you wish to pull your pertinent data from HealthVault into TMD, you can do it here by clicking the HealthVault button.

**Tracking My Diabetes**

Welcome mswalker ( Settings | Logoff )
Last sign in: 09/20/2012 at 12:03 PM

Overview ⋮ Healthy Eating ⋮ Being Active ⋮ Medications ⋮ Blood Sugar ⋮ Weight ⋮ Outlook

## Overview

### Welcome to Tracking My Diabetes!

Add SMBG
Food
Activity
Medication
Weight

### Tip of the Week

Burnout happens. It happens when you get tired of sticking to your regular routine of checking blood sugars, exercising, and eating right. One way to deal with burnout is to give yourself a break. Some days will be better than others. Try to learn from your mistakes instead of beating yourself up.

## Things To Do

Brief Illness Perception (B-IPQ)
Exercise week 1
Add Appointment
Add LDL Lab
Add A1C Lab
Add Physical Activity
Add Snack/Meal
Add Medication
Add Weight
Add SMBG

Add SMBG | Food | Activity | Medication | Weight

### Activity Listing

No Activity Listings Exist.

### Appointments

| Last Appointment | Appointment Type | Next Scheduled Appt |
|---|---|---|
| Not Entered | ● Dental Exam | Add Appointment |
| Not Entered | ● Eye Exam | Add Appointment |
| Not Entered | ● Foot Exam | Add Appointment |
| Not Entered | ● Primary Care | Add Appointment |

### Labs

There are no labs entered. Please enter your most recent lab values so we can generate accurate feedback and advice.

Add Lab

| Self Reported | Last Activity |
|---|---|
| Overview | Never |
| Healthy Eating | Never |
| Being Active | Never |
| Medications | Never |
| Blood Sugar | Never |
| Weight | 7 days ago. |

Microsoft® HealthVault™

Help

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Making and keeping regular screening exams is an essential part of preventing the complications of diabetes! To add an appointment, look at the lower left half of the Overview page, Appointments provides a space for you to record the dates of your last dental, eye, foot and primary care appointments. Clicking on Add Apointment brings up a box for you to enter the specifics.



**Add Appointment**

* Type: Type
* Date/When:          * Time: HH : MM AM
* Who:
* Where:
Notes:

Save   Close

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Selecting Healthy Eating from the overview page opens up your Healthy Eating Diary and displays the Tip of the Week.



Selections under Meal Examples display sample meal plans and calories. The purpose of this is to help you in completing your Healthy Eating Diary, which is intentionally simple, asking only for which meal, the approximate size of the meal, and whether you thought it was healthy or not (or mixed).
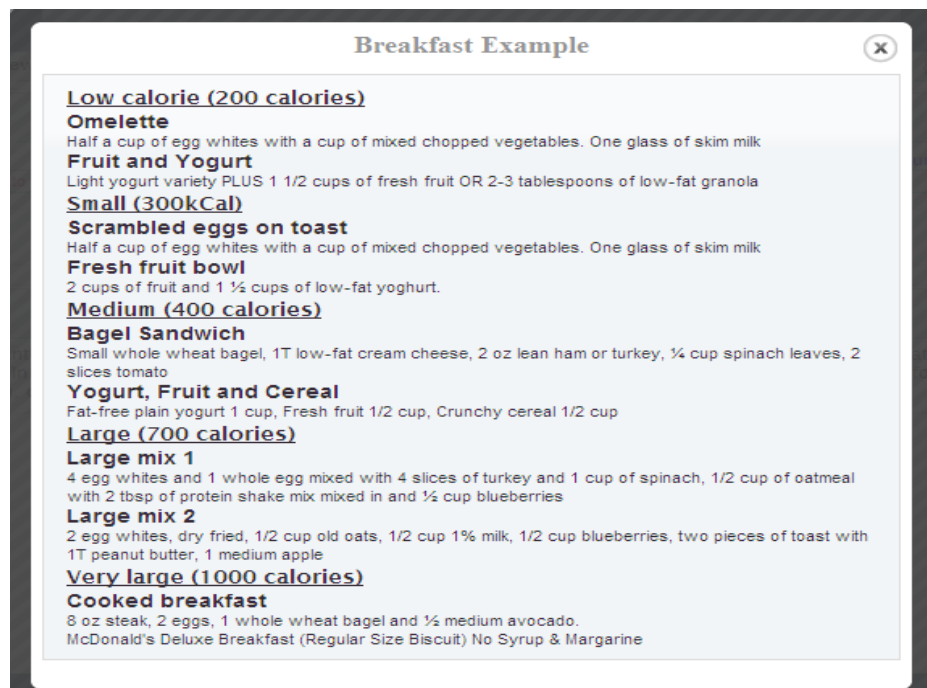
Clicking Add Meal/Snack opens up to a page with the current date and space to record the time that you ate, the amount that you ate (small, medium, large, very large), and whether it was healthy, unhealthy, mixed, or you are not sure.



Select Add Snack/Drink to open up additional space to document additional snacks or drinks. Select save after each entry and close when you are finished.

Selecting Outlook will open up to a page that includes the tip of the week and several surveys that you can take. You will be prompted monthly to complete a survey, but you can choose to take one at any time as well. The surveys ask questions about what you find difficult about the various diabetes self care tasks like testing your blood sugar or taking your medications.There are also surveys that ask what you believe about diabetes and how your mood has been. When you complete a survey, you will be given specific feedback that is intended to encourage you and/or provide suggestions about how to cope with problems you might be facing. A list of the surveys is on the next page.

**Tip of the Week**

Burnout happens. It happens when you get tired of sticking to your regular routine of checking blood sugars, exercising, and eating right. One way to deal with burnout is to give yourself a break. Some days will be better than others. Try to learn from your mistakes instead of beating yourself up.

**Surveys You Can Take**

| Survey | Text |
|---|---|
| Food Survey | This is your a brief, weekly survey of your diet during the past week. The surveys differ from week-to-week. They all help to structure the feedback that you receive about healthy eating. |
| Exercise Survey | This is your a brief, weekly survey of your physical activity during the past week. The surveys differ from week-to-week. They all help to structure the feedback that you receive about your physical activity. |
| Brief Illness Perception (B-IPQ) | This is a short survey that asks about your beliefs about diabetes. Often the beliefs we have about our health affect how we take care of ourselves. The survey has 6 questions. |
| Epidemiologic Studies – Depression (CESD) | This next survey asks about how your mood has been lately. Sometimes our mood affects how we take care of ourselves, and sometimes how we take care of ourselves affects our mood! So it is important to know what are mood is like. There are 20 questions about how you have felt and behaved during the last week. |
| Diabetes Distress Screener | Living with diabetes can sometimes be tough, with lots of hassles and problems that come and go. This next survey asks about things about your diabetes that might have bothered you during the past month. If you feel that a particular item is not a bother or problem for you, choose '1'. If it is very bothersome to you, choose '6' |
| Environmental Barriers (Medication) | Taking medications can be an important part of diabetes care. The next his survey is to identify any problems you might be having taking medications as prescribed. |
| Environmental Barriers (Exercising) | Exercise is important for lowering or maintaining weight, improving cardiovascular health, and lowering blood sugar. This survey is to identify any obstacles to exercise that you might have. |
| Environmental Barriers (Testing SMBG) | Testing your blood sugar can tell you and your health care provider about how your medications are working, how the food you eat affects you, and how the exercise you do helps you. So testing your blood sugar is important! This survey is to see if you have any problems with testing your blood sugar, and what those problems are. |
| Environmental Barriers (Eating) | This survey asks about any problems you might have eating the way you think you should, or sticking to your diet plan. It asks about such problems because what and how much you eat might affect your diabetes more than anything else you do. |

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If you place your mouse on and double click a survey, it will open for you to complete. The example below shows what happens when we click on the survey named Brief Illness Perception (B-IPQ).

The Being Active tab has a format and function similar to the Healthy Eating tab in that it is intended to be simple for you to use, allows you to enter activity you do with a self-rating of exertion, gives feedback on the data that you enter, and provides a tip of the week. The two screen shots below show, first, the first page of the Being Active tab and, second, the box for entering activity.
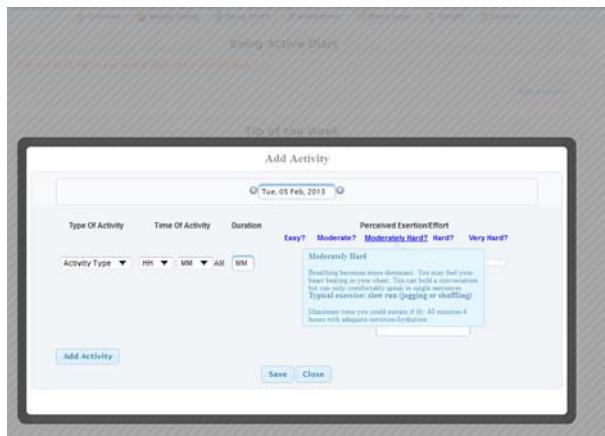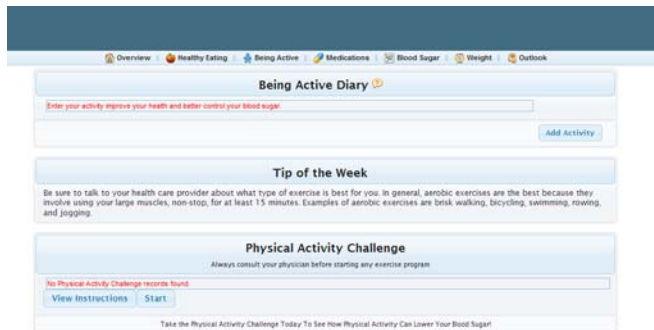




The Being Active tab also includes monthly physical activity challenges, to keep you interested and 'on your toes', and to show the relationship between physical and activity and blood glucose, among other things. You will be prompted to complete these regularly. You can choose to ignore them, if you wish.

Every week, you will also be asked to complete brief surveys (about 5 questions) about your diet and physical activity.

The Medications tab allows you to enter the *diabetes* medications that you are taking so that you can track (such as on your smartphone) when you take them and can received reminders and education about medications. This functionality is shown in the next two graphics. The Medications tab also includes a tip of the week.

The last tab we will show you is the Blood Sugar tab. You can either upload your meter readings via Microsoft HealthVault, if you have an account there, or you can enter your readings one at a time.

Once you have self-monitoring (SMBG) data in TMD, you will be able to look at graphs of your glucose trends (highs, lows, etc.) and will be able to overlay (with a graph) your trends on your Food Diary, Activity Diary, and Medications Log to see how those components of diabetes self-care affect your blood sugar.

As with the other tabs, the Blood Sugar tab includes a tip of the week.

For now, we are not reviewing the functionality of the Weight tab, since we don't want you to address weight until you have used TMD for at least 6 weeks and recorded your weight every week as prompted.



### TASK 5. Develop protocol and obtain approval from all appropriate Institutional Review Boards for Pilot Study of Version 2 PHR-A – NOT COMPLETED

In May 2011, with the cessation of operations at TRUE Research Foundation, we submitted at revision to the Statement of Work through the Geneva Foundation. This was necessary to a) transfer the remaining funds and b) to adjust to the reduction in budget that was "lost" (never spent by the project) at TRUE. The Revisions to the Statement of Work pertain to Tasks 5 – 7. The revision was approved in August when the funds were officially transferred to Geneva.

In brief, we proposed to modify the study design of the Pilot. These changes included:

1) Reduce duration of the study from 6 months to 3 months. Three months is the minimum period to observe clinically meaningful changes in diabetes-related outcomes, namely A1c.

2) Reduce the sample size from 90 (45 per arm) to 32 per arm. This estimate is based on the following assumptions: alpha = 0.05 (two-sided); power = 0.80, mean decline in A1c for PHR-A group = 1.0 (sd = 1.0); mean decline in A1c for attention control group = 0.5 (sd = 0.50); n2/n1 = 1.00; number of follow-up measurements = 1; number of baseline measurements = 1; correlation between baseline & follow-up = 0.60; method of analysis = change.

Although a larger sample size (e.g., the one originally proposed!) would have been our preference given how important larger samples are for statistically controlling for certain subject characteristics (e.g., age, type of diabetes, etc.), this smaller sample is sufficient for a basic test of the hypotheses and is consistent with related studies, such as that

published in *Diabetes Technology and Therapeutics* regarding a mobile diabetes application called "WellDoc" (Quinn et al.. WellDoc™ Mobile Diabetes Management Randomized Controlled Trial: Change in Clinical and Behavioral Outcomes and Patient and Physician Satisfaction. *Diabetes Technology and Therapeutics* 2008; 10: 160-168.).

3) Require that all study participants have their own smart phones or that they will access the application via an Internet-connected computer.

In brief, for the Pilot Study, we were going to recruit people with diabetes and randomly allocate them to use the PHR-A for 3 months or to 'attention control.' After confirming eligibility using some simple tests of manual dexterity and cognitive function, we were going to collect metrics on the subjects' backgrounds, glycemic control (A1c and self-monitoring of blood glucose data), self-reported self-care [Summary of Diabetes Self-Care Activities (SDSCA)], and diabetes-related distress [Problem Areas in Diabetes (PAID) scale]. At various points throughout the study, we were going to repeat collection of A1c, self-monitoring of blood glucose data, SDSCA, and PAID, and measure subjects' engagement by tracking the contacts that they initiate with their providers and their adherence to appointments. At the completion of data collection, we were going to analyze the data with t-tests, repeated measures ANOVA, and multinomial logistic regression models.

With this revised Pilot Study in mind, we wrote the protocol documents for submission at Womack at Fort Bragg in NC. Our contact there was Dr. Laura Bowers. We submitted a Revision to the Statement of Work at the end of the Period of Performance to conduct the study at Womack, and this was approved by TATRC.

Then the project hit two substantial roadblocks. First, the full transfer to Womack never occurred, because their leadership changed their minds. So we elected to move the study back to Walter Reed, despite problems with our local IRB and the challenges of having many clinical trials running concurrently in the same clinic.

Soon after the decision to move the study back to Walter Reed, Dr. Vigersky, the founder, director, scientific leadership of the Diabetes Institute at Walter Reed announced that he would be leaving the military and will no longer be able to participate in this project. In conjunction, other members of the Diabetes Institute were set to relocate to other departments within Walter Reed, primarily due to funding concerns and the changing of the structure of the Diabetes Institute. Thus, the team to support this project by identifying potential subjects, assisting with paperwork, providing space for appointments, etc. was drastically cut.

The new director of the Diabetes Institute indicated that she was unable to oversee all the projects currently ongoing or planned for the Diabetes Institute.

Dr. Fonda and other Geneva staff determined, therefore, that the best course of action is to close down the project and return unexpended funds.

### *TASK 6. Initiate and maintain Pilot Study through Completion—NOT COMPLETED*

This Task was dependent on the preceding task and not completed.


### *TASK 7. Prepare reports and manuscripts for presentation at national meetings regarding the technology and our findings from the Pilot Study— NOT COMPLETED*

This Task was dependent on the preceding task and not completed.

**KEY RESEARCH ACCOMPLISHMENTS:**

- Finalization of the rubric for the PHR-A (e.g., modules for Healthy Eating, Being Active, Monitoring of Blood Glucose, etc.)
- Document with functional requirements
- Determination of how users will do manual data entry, as needed
- Drafting and documentation of rules and algorithms for specific components/modules of the PHR-A
- Drafting of code for the components of the PHR-A based on the written rules and algorithms, leading to a Version 1
- Drafting of over 200 tips that pertain to each component of the PHR-A
- Documentation of code establishing linkages between the PHR-A and a PHR – Microsoft HealthVault only
- Solicitation of and receipt of feedback on the PHR-A from experts, namely people who care for people with diabetes and people who have diabetes
- Revision of the PHR-A (feedback, surveys, tips, introduction to each section and task), leading to a Version 2
- Transfer of funds from TRUE Research Foundation to the Geneva Foundation, with re-establishment of sub-contracts, etc.
- Establishment of a final site for the Internet "presence" to host the PHR-A and a new name, called Tracking My Diabetes-- **http://trackingmydiabetes.com**
- Revision to the design of the Pilot Study, to better fit the reduction in budget and time resulting from the cessation of operations at TRUE Research Foundation
- Presentations about the PHR-A at national meetings
- Further revision of a pilot study – but this was not completed. The documents are available for use by someone with adequate financial, clinical, and research support.


**REPORTABLE OUTCOMES:**

The following publications reference design aspects of the PHR-A:

Fonda SJ, Kedziora RJ, Vigersky RA, Bursell SE. Evolution of a web-based, prototype Personal Health Application for diabetes self-management. *Journal of Biomedical Informatics* 2010; 43: S17 – S21*.*

Although it was not the focus of the talk, the following presentation included mention of the PHR-A concept and our development efforts to date:

Invited presentation, "e-, i-, or m-health? Blurring Boundaries between Provider and Patient-Centered Management". Annual Meeting of the Diabetes Technology Society, November 13, 2010.


**CONCLUSION:**

Reduction or prevention of diabetes-related complications requires blood glucose levels be kept as close as possible to the normal range. Daily self-care behaviors carried out by the person with diabetes are of central importance in attaining good blood glucose;

however, many people struggle with appropriate or consistent self-care. Tools have evolved over the past decade to help with diabetes self-care, but they are either tied to a clinic or provider, do not make use of Personal Health Records (PHR) as a place for storing and accessing useful diabetes data (such as Microsoft HealthVault), lack decision support, or some combination of these things. A new tool for diabetes care that can be mobile, if desired, uses a PHR, is not tied to a clinic, and can provide decision support with actionable recommendations is needed.

Thus, our objective is to develop a new tool for diabetes self-management, involving potential end-users in the process, and to conduct a Pilot Study of the efficacy of the new tool. The new tool is called Tracking My Diabetes (TMD). For the Pilot Study, our central hypothesis is that a PHR-A (TMD) that coordinates the major components of diabetes self-management, is mobile, provides decision support with actionable options, and is based on user input will enhance diabetes self-care, improve glycemic control, and lower psychological distress related to diabetes.

Our specific aims in this project are to develop a new PHR-A for diabetes self-management, to obtain feedback of this product regarding its "look and feel", and then to conduct a Pilot Study with people with diabetes that will test the following hypotheses: 1) Glycemic control will be more improved among people with diabetes who receive the PHR-A compared with people with diabetes who receive "attention control".; and 2) Self-reported diabetes self-care, engagement with care, and psychological distress related to diabetes will be more improved among people with diabetes who receive the PHR-A compared with people with diabetes who receive "attention control.

The project had a late start due to errors in the contract and then experienced a cessation of operations from April to August 2011 when TRUE Research Foundation declared bankruptcy. However, we have completed ALL development and have written a revised research protocol for the proposed Pilot Study, to be conducted at Womack, all things going as planned.  In the coming year, we plan to conduct the Pilot Study.

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**APPENDICES:**

None.

**SUPPORTING DATA:**

None.